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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,229	08/23/2001	Mohammed El-Sherbeini	20193P	8700
210	7590	04/08/2004	EXAMINER	
MERCK AND CO INC			PORTNER, VIRGINIA ALLEN	
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RAHWAY, NJ 070650907			PAPER NUMBER	
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DATE MAILED: 04/08/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,229

Applicant(s)

EL-SHERBEINI ET AL.

Examiner

Ginny Portner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 12/18/2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 8-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> . |

DETAILED ACTION

Claims 1-7 are under consideration; claims 1, and 4-6 have been amended.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections Withdrawn

2. Claims 5 and 6 are not longer directed to non-statutory subject matter.

3. Claim 4 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been obviated through amendment of claim 4 to clarify the claimed invention through the recitation of a "wherein" clause, thus further limiting claim 1 from which claim 4 depends and has been amended in such a way that SEQ ID No 1 need not evidence antecedent basis in claim 1 as the recitation of SEQ ID NO 1 in claim 4 further limits claim 1.

Objections/Rejections Maintained

4. The disclosure is objected to because of the following informalities: At page 1, lines 28-29 the phrase "—a single molecule composed of peptidoglycan—" is still recited; no clarification or removal of the " - - " marks were submitted. Appropriate correction is required.

5. Claims 1-3, 5-6 rejected under 35 U.S.C. 102(e) as being anticipated by Hoskins et al (US Pat. 5,834,27; effective filing date June 18, 1996), for reasons of record in paper number 8, dated September 9, 2003, paragraph 11 and arguments set forth below.

6. Claims 1-7 rejected under 35 U.S.C. 102(e) as being anticipated by Rubenfield et al (US Pat. 6,551,795, effective filing date February 18, 1998).

7.

Response to Arguments

8. Applicant's arguments filed December 18, 2003 have been fully considered but they are not persuasive.

9. The disclosure objected to because of the following informalities: At page 1, lines 28-29 the phrase "—a single molecule composed of peptidoglycan—" is still recited; no clarification or removal of the " - - " marks were provided in Applicant's Remarks and is therefore maintained for reasons of record in paper number 8.

10. The rejection of claims 1-3, 5-6 under 35 U.S.C. 102(e) as being anticipated by Hoskins et al (US Pat. 5,834,27; effective filing date June 18, 1996), is traversed on the grounds that:

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Claim 1 has been amended to remove the recitation of a polynucleotide having at least 25 nucleotides; and requests that this rejection be withdrawn as moot.

11. It is the position of the examiner that Hoskins et al still anticipates the claimed invention based upon the definitions provided for the scope of what is now claimed.

At page 6, lines 3-5, the embodiment claimed in claim 1, paragraph (a), is set forth. The polynucleotide of the claimed invention is further defined in the specification at page 9, lines 16-21, to include “a nucleic acid of more than one nucleotide”, and the polypeptides of the instant invention are encoded by the claimed polynucleotide include “biologically active fragments and mutant or polymorphic forms of MurD polypeptide sequences of SEQ ID NO:2, including but not limited to amino acid substitutions, deletions, additions, amino terminal truncations, and carboxy-terminal truncations such that these mutations provide for proteins or protein fragments of diagnostic, therapeutic or prophylactic use and would be useful for screening for modulators, and/or inhibitors of MurD function (instant Specification at page 12, paragraph 1). Therefore, any polynucleotide sequence that encodes any size amino acid sequence of a MurD analog or homologue polypeptide (definition provided at page 13, bottom paragraph) is within the scope of the claimed invention.

12. The nucleic acid sequence of Hoskins et al encodes a polypeptide of MurD biological activity and represents a functional homolog and mutant analog of the instantly claimed polynucleotides and also encodes an amino acid sequence of SEQ ID No 2, thus meeting the definitions of the instant specification.

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13. The polynucleotides of Hoskins et al encodes an amino acid sequence of SEQ ID NO 2, at numerous locations of SEQ ID NO 1 (Hoskins et al, see alignment provided showing the polynucleotide sequence of Hoskins et al encodes an amino acid sequence of SEQ ID NO 2).

Hoskins et al still anticipates the instantly claimed invention as now claimed, despite the fact that the claims no longer recite the phrase “at least 25 nucleotides” and “naturally occurring mutant”. The polypeptide of the claims is not required by the claims to evidence any specific biological function (claims 1-6), but based upon the definitions provided by the specification, a species within the instantly claimed genus of polynucleotides are homologue polynucleotides that encode MurD polypeptides that comprise an amino acid sequence of SEQ ID No 2, but are also mutants of SEQ ID NO 2. The sequence of Hoskins et al does not share 100% sequence identity with SEQ Id NO 2, thus defining a mutant form of SEQ ID NO 2, which polynucleotide encodes a functional homologue polypeptide that evidences the same or equivalent MurD biological function.

14. The rejection of claims 1-7 under 35 U.S.C. 102(e) as being anticipated by Rubenfield et al (US Pat. 6,551,795, effective filing date February 18, 1998) is traversed on the grounds that Rubenfield cites two priority dates and the Examiner has not pointed out to Applicant whether sequence 7702 was present in the application as filed on 02/18/1998.

15. It is the position of the Examiner that polynucleotides sequences 1-7892 evidenced original descriptive support in the earliest priority document and sequences 7702 was presented in Table 2, page 455 (copies of provisional Application pages provided herewith). Additional sequences which evidence sequence identity with Applicants SEQ ID Nos 1 and encode an

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amino acid sequence of SEQ ID NO 2 applied against the claims were SEQ ID Nos 7552; 7623; 7624 and 7787. Originally presented claims in the earliest priority document claimed polynucleotides sequences complimentary to the disclosed coding sequences. Therefore the sequences of Rubenfield et al still anticipate the instantly claimed invention under 35 USC 102(e).

New Claim Limitations/New Grounds of Rejection

Claim Rejections - 35 USC § 112

16. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

17. Claims 1-7 have been amended to recite the phrase “fully complementary”. What this phrase means is not defined in the instant specification and the polynucleotides of paragraph (a) are not limited to just polynucleotides that encode SEQ ID NO 2, but are directed to polynucleotides that encode a polypeptide that has “an amino acid sequence of SEQ ID NO:2”. The polypeptide not being required by the claims to evidence any specific biological function and is so claimed to comprise additional nucleotides that do not encode any portion of SEQ ID NO 2. Therefore the polynucleotide sequence encompassed by the claim limitations set forth in paragraph (a) to which the polynucleotide of paragraph (b) is fully complementary is not clearly and distinctly set forth in the claims. What constitutes a polynucleotide that is not fully complementary? What is the complete sequence of the polynucleotide sequence of paragraph (a) that is not fully claimed to encode any specific polypeptide of any specific biological function,

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but is directed to encoding any polypeptide that encodes any portion of the amino acid sequence of SEQ Id NO 2?

18. Claim 2 broadens the scope of claim 1 through the recitation of “non-natural or modified nucleotides” as claim 1 does not define within the scope of the claim “non-natural or modified nucleotides”, but only polynucleotides that encode an amino acid of SEQ ID NO 2. SEQ ID NO 2 does not comprise any non-natural or modified nucleotides. Claim 2 is not further limiting of claim 1, as it sets forth a genus that contains additional variant polynucleotides, thus defining a larger genus of polynucleotides. The recitation of “mutant or polymorphic form” which previously provided for the presence of non-natural linkages has been canceled by Applicant’s Amendment. It also is not clear whether the non-natural or modified nucleotides are those which encode an amino acid sequence or have been added in addition the polynucleotide that encode a polypeptide with an amino acid sequence of SEQ ID NO 2. How do the non-natural or modified nucleotides permit the utilization of the claimed polynucleotide to be used in the claimed method of producing a MurD protein? Has the correct open reading frame been maintained when the non-natural or modified nucleotides (instant claim 2) or linkages (instant claim 3) have been introduced?

19. Claim 3 broadens the scope of claim 1 by defining a genus that comprises non-natural linkages which are not present in the polynucleotide that encodes an amino acid sequence of SEQ ID NO 2. The recitation of “mutant or polymorphic form” which previously provided for the presence of non-natural linkages has been canceled by Applicant’s Amendment.

20. Claim 6 recites the indefinite article “a”; claim 6 should recite the term —the— to be definite. Additionally, claim 6 recites the term “heterologous”; this term lacks antecedent basis

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in claim 5 from which it depends. In light of claim 5 having been amended to recite the phrase isolated and purified, the host cell of claim 6 should recite: --A host cell comprising the expression vector of claim 5, wherein the expression vector is an heterologous expression vector--.

21. Claim 7 depends from claim 5, and is directed to a process for expressing a MurD protein. The term "MurD" lacks antecedent basis in claims 5 and 1 as the claims do not require the claimed polynucleotide to encode a MurD polypeptide. The term "murD" was canceled from claim 1 by Applicant's amendment. The polynucleotide now claimed is not required to encode a polypeptide of any specific biological function. While the polynucleotide of claim 5 could be expressed, it is not required to encode a *Pseudomonas aeruginosa* MurD protein. How do the polypeptide encoded by the polynucleotide of claim 1 differ in structure to the protein of claim 7; how are they the same? The term "protein" lacks antecedent basis in claims 5 and 1 from which claim 7 directly or indirectly depends.

22. Claim 7 also recites the phrase "suitable host cell". What makes the suitable host cell suitable? The term "suitable" in claim 7 is a relative term which renders the claim indefinite. The term "suitable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The meets and bounds of the claims relative to the recitation of what is suitable are unclear.

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Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Vgp

April 2, 2004


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Continuation of Attachment(s) 6). Other: additional pages attached to Office Action.